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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,616	07/02/2001	Aprile L. Pilon	116142/00170	3118

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EXAMINER

LEE, BETTY L

ART UNIT PAPER NUMBER

1647

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/898,616

Applicant(s)

PILON ET AL.

Examiner

Betty Lee, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 35-55, 74-78 and 101-103 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35-55, 74-78 and 101-103 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 7/22/05.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

The amendment filed 07/22/05 has been entered. Claims 1-103 are pending. Claims 1-34, 56-73 and 79-100 have been withdrawn from consideration as directed to non-elected subject matter. Claims 35-55, 74-78 and 101-103 are under examination. The text of those sections of Title 35 U.S. Code, not included in this action can be found in a prior office action.

### ***Informalities***

References 1-114 on pages 2-8 of the information disclosure statement (IDS) filed 7/22/05 fail to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the references were not included with the IDS. The IDS has been placed in the application file, but the information referred to therein has not been considered as to the merits. Only the patents and foreign patents listed on pg 1 and the last page have been considered. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

### ***Claim Rejections/Objections Maintained***

#### ***Claim Rejections - 35 USC § 112***

The rejection of claim 36 under 35 U.S.C. 112, second paragraph, is maintained for reasons of record. Sequence Identifiers (SEQ ID Nos.) denote nucleic acid sequences, not genes per se. It is not clear if applicant intends the synthetic gene to consist of the nucleotide sequence of SEQ ID NO: 1, 2, 3, or 4 or whether the term "gene" denotes that other (unidentified) components may be present. The metes and bounds of what a synthetic gene encompasses are unclear.

The rejection of claim 50 under 35 U.S.C. 112, second paragraph, is maintained for reasons of record because the amended claim still has the phrase 'SEQ ID Nos 1-4'.

The rejection of claims 74-78 is maintained for reasons of record. The amendment to claim 74 with the phrase ' a step of claim 35 which precedes the step within the process of claim 35 from which said samples of intermediates were taken' is still indefinite. Claim 35 does not include any step (a-i) that mentions 'intermediates' and it is unclear when the samples of intermediates can be taken. Therefore, the rejection is maintained.

### ***Claim Rejections - 35 USC § 103***

The rejection of claim 49 under 35 U.S.C. 103(a) as unpatentable over Torkkeli *et al* (Biochim. Biophys Acta 544(3): 578-592, 1978) in view of Anderssson *et al* (J. Biol. Chem. 269 (29):19081-19087, 1994) and Mourot *et al* (Separation Science and Technology 24(5&6):353-367, 1989) is maintained for the reasons of record. Additionally, newly added claim 102 is rejected as unpatentable over Torkkeli *et al* (Biochim. Biophys Acta 544(3): 578-592, 1978) in view of Anderssson *et al* (J. Biol. Chem. 269 (29):19081-19087, 1994) and Mourot *et al* (Separation Science and Technology 24(5&6):353-367, 1989) for the same reasons.

Applicant failed to address the grounds of rejection in the amendment filed 7/22/05.

The rejection of claim 55 under U.S.C. 103 (a) as unpatentable over Andersson *et al* in view of Palmer *et al* (US Patent 4691009) and Shin is maintained for the reasons of record. Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues that Andersson *et al* does not disclose or suggest the production of pharmaceutical grade rhUG, which is substantially free of endotoxin, nucleic acid and other contaminants. Applicant further argues that neither Palmer *et al* nor Shin *et al* teach the production of pharmaceutical grade rhUG. However, applicant's arguments are not commensurate in scope with the claim. The instant specification does not define the 'pharmaceutical grade' as meaning 'free of endotoxin, nucleic acid and other contaminants'. Motivation to make large quantities of pharmaceutical grade

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rhUG is provided by Andersson *et al* who teaches that large quantities of purified recombinant uteroglobin are desirable. As Palmer *et al* teach large scale production of recombinant proteins in fermenters and Shin *et al* teach fermentation as a key bioprocess technology for producing recombinant human insulin for the pharmaceutical industry, it would have been obvious for a person of ordinary skill in the art to combine their teachings. One of ordinary skill in the art would have had a reasonable expectation of success in obtaining pharmaceutical grade rhUG.

### ***Double Patenting Maintained***

The rejection of claims 35-55 and 74-78 under 35 U.S.C. 101 as being unpatentable over claims 35-41, 48-61 and 80-84 of copending Application No. 10187498 as claiming the same invention is maintained.

Applicant's request that the examiner hold the double patenting rejection in abeyance is noted; however, the provisional rejection is maintained until such time as the duplicate claims are removed from one of the conflicting applications.

### ***New Claim Rejections Based on Amendments***

#### ***Double Patenting***

Claims 101-103 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 85-122 of copending Application No. 10187498. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 101-103 are drawn to a 'purified rhUG of pharmaceutical grade' and claims 85-122 of the copending application are drawn to a pharmaceutical composition comprising of purified rhUG.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 42 and 52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. The phrase 'having an ionic capacity of between about 325 and about 475  $\mu\text{eq}$ ' is new matter as the range does not appear to enjoy support in the original specification. This matter might be resolved if applicant were to point out where in the specification support for the newly recited material can be found.

***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Betty Lee, Ph.D. whose telephone number is (571) 272-8152. The examiner can normally be reached on M-F 9 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BLL

  
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